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10/520,100	01/04/2005	Masaya Tanaka	0020-5551PUS1	6992
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BIRCH STEWART KOLASCH & BIRCH			EXAMINER	
PO BOX 747			KASSA, TIGABU	
FALLS CHURCH, VA 22040-0747			ART UNIT	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/520,100	Applicant(s) TANAKA, MASAYA
	Examiner TIGABU KASSA	Art Unit 1619

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED. (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(o).

Status

- 1) Responsive to communication(s) filed on 15 September 2008.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 13-24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 13-24 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
 3) Information Disclosure Statement(s) (PTO-1449)
 Paper No(s)/Mail Date 11/28/2007 and 01/04/05.
- 4) Interview Summary (PTO-413)
 Paper No(s)/Mail Date. _____.
- 5) Notice of Informal Patent Application
- 6) Other: _____.

DETAILED ACTION

This Office Action is in response to the amendment filed September 15, 2008. Claims 13-24 are pending. Claims 13-24 are under consideration in the instant office action. Claims 1-12 are cancelled. Receipt and consideration of Applicants' amended claim set and arguments/remarks submitted on September 15, 2008 is acknowledged. Applicants amended claim set have necessitated new rejections (e.g. 103).

Note: The scope of instant claims 13-24 is exactly the same as the cancelled claims 1-12 except that instant claims 13-24 are rewritten correcting idiomatic English.

Moot Rejections/objections

All rejections and/or objections of claims 1-12 cited in the previous office action mailed on May 13, 2008 are moot, because said claims have been cancelled.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 13-24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "substantially" in claims 13-24 is a relative term which renders the claim indefinite. The term "substantially" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would

not be reasonably apprised of the scope of the invention. The amount of carbon dioxide in non-bubble state, defined by "substantially" is indefinite.

The term "sheet-like" in claim 14 is vague and indefinite. The phrase is not defined by the claim, the specification does not provide a standard for ascertaining what type of materials "sheet-like" refers to. One of ordinary skill in the art would not be reasonably apprised of the scope of the meaning of the term.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later

invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 13-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tanaka et al. (WO 99/24043) using (U.S. patent No. 6,689,339 as translation of WO 99/24043) and as evidenced by Kenneth N Anderson et al., Mosby's Medical, Nursing, and Allied Health dictionary 1528 (Mosby 5th ed. 1998) and in view of Gibbins et al. (WO 01/49258).

Applicant Claims

Applicant claims in instant claim 13 a material for formation of carbon dioxide external preparation, characterized by comprising: a base agent that comprises a polymeric three-dimensional network structure impregnated with a viscous material containing at least an acid and water, and is made to contact with the skin in use; and a reactant that contains at least a carbonate, and is made to contact with the base agent in use so as to generate carbon dioxide, the carbon dioxide dissolving in the viscous material substantially in a non-bubble state. Instant claims 14-15, 18, and 22-23 recite about different features of the polymeric three-dimensional network structure being sheet-like, a fibrous or porous absorbent, and a non woven cloth or a sponge. Instant claim 16 recites possible thickener types. Instant claim 17 recites the material for preparing an external preparation containing carbon dioxide according to claim 13, wherein the viscous material is an emulsion or cream containing at least an acid, water, an oil and a surfactant. Instant claim 19 recites wherein the reactant is a viscous material further containing a thickener and water. Instant claims 20-21 recite lists of thickeners carbonate types, acid types, the elastic polymeric three-dimensional network structure types. Instant claim 24 recites an

external preparation containing carbon dioxide substantially in a non-bubble state, which is obtained during use of the material according to any one of claims 13 through 23.

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

Tanaka et al. (WO 99/24043) disclose “viscous compositions containing carbon dioxide, formed by incorporating carbon dioxide in the form of bubbles in a water-containing viscous composition containing one or more thickener(s)” (column 2, lines 37-41) for mucocutaneous or transmucosal absorption of carbon dioxide. Tanaka et al. also discloses kits for carbon dioxide external use, comprising carbonate salt and a water-containing viscous composition (column 3, lines 40-45). Tanaka et al. ('043) also state that the “carbon dioxide is generated by a reaction between an acid and a carbonate salt (column 3, lines 14-18). Tanaka et al. (WO 99/24043) also disclose that the composition may be applied to a part of the body directly, by impregnating the viscous composition using an absorbent material such as a gauze or sponge (column 11, lines 4-5). “A sponge is defined as a resilient absorbent mass used to absorb fluids, to apply medication, or to cleanse. It may be manufactured from cellulose, rubber, or synthetic material” (Kenneth N. Anderson et al., *Mosby's Medical, Nursing, and Allied Health Dictionary* p1528 (Mosby 5th ed. 1998)). Thus, the sponge of Tanaka et al would necessarily be a polymeric three-dimensional network structure as recited. Furthermore, since carbon dioxide is somewhat soluble in aqueous solutions, the product of Tanaka et al. would necessarily include at least some carbon dioxide in a non-bubble state.

Tanaka et al teach a material for formation of a carbon dioxide external preparation that includes a viscous material containing at least an acid and water (column 3, lines 39-40) and a reactant that contains carbonate (column 3, lines 39). Prior to use, the carbonate is reacted with

the viscous material which produces a carbon dioxide containing product and the product is contacted with skin using a gauze or sponge that is impregnated with the product (column 11, lines 4-6), which addresses instant claim 13.

As per the disclosure by Tanaka et al. for the possibility of impregnating the viscous composition using an absorbent material such as a gauze or sponge or by patching a bag made of the absorbent material wherein the composition is filled (column 11, lines 4-6), a sponge is a polymeric three-dimensional network, which can be sheet-like, fibrous or porous absorbent, which addresses instant claims 14-15, 18, and 22.

Tanaka et al. also disclose a list of thickeners which can be natural polymers, semi-synthetic polymers, or inorganic substances (column 2, lines 42-46). For natural polymers used as a thickener (gum Arabic, carrageenan, galactan.....) (column 2, lines 47-55), for the semi-synthetic polymer used as a thickener (ethyl cellulose, carboxymethyl cellulose and salts thereof....) (column 2, lines 55-67 and column 3, lines 1-2), and for synthetic polymer used as a thickener (carboxyvinyl polymer, sodium polyacrylate, polyvinylacetaldieethylaminoacetate, polyvinyl alcohol, polyvinyl pyrrolidone....), which addresses instant claims 16,18, 20, and 21.

Furthermore, Tanaka et al. also mention a list of acids that can be used for the generation of carbon dioxide (formic acid, acetic acid, propionic acid, butyric acid, valeric acid, oxalic acid, malonic acid, succinic acid, glutaric acid....)(column 3, lines 19-34), and also a list of carbonates ammonium carbonate, potassium carbonate, calcium carbonate, sodium carbonate, sodium bicarbonate, potassium bicarbonate, potassium sesquicarbonate...) (column 3, lines 35-38), which addresses instant claims 18 and 21.

Tanaka et al. teach that the viscous composition containing at least an acid, water, an oil or and a surfactant can be applied for treating the mucocutaneous or injured tissue, hair, etc in the form of gel, cream, paste, mousse or the like (column 6, lines 37-39), which addresses instant claim 17.

Tanaka et al. disclose a kit containing an aqueous viscous composition comprising a carbonate or carbonates, an acid or acids, a thickener or thickeners and water (column 4, lines 4-6), which addresses instant claim 19.

Tanaka et al. disclose a kit comprising an acid-containing aqueous viscous composition and carbonate-containing sheet (column 6, lines 60-61), which addresses instant claim 22.

Additionally, Tanaka et al also disclose that the part of the body to which the composition is applied is covered with a film of poor permeability or dressing material (column 11, lines 9-11), which addresses instant claim 23.

*Ascertainment of the Difference Between Scope the Prior Art and the Claims
(MPEP §2141.012)*

Tanaka et al does not explicitly teach the viscous material being initially impregnated in a polymeric three-dimensional network structure prior to reacting it with the carbonate. This deficiency is cured by the teachings of Gibbins et al.

Gibbins et al disclose matrices such as polyacrylamide and a non-gellable mucopolysaccharide, which are polymeric three-dimensional network structures, being used to trap a gas generated after a reaction between two different reactants (page 18, lines 7-11). Gibbins et al (WO 01/49258) disclose that the gas bubbles are generated by the permeation of the second reactant added to the formed matrix that contains the first reactant (page 18, lines 13-14). The reaction between the two reactants *in situ* results in the liberation of gas which is entrapped

within the matrix (page 18, lines 14-16). Gibbins et al (WO 01/49258) also disclose the possibility of incorporating an active agent with the second reactant, which is similar to the viscous composition in the instant application (page 18, lines 10-11). Gibbins et al (WO 01/49258) also mention that the composition can be added to the preformed matrix either simultaneously or sequentially, for perfusion within the matrix (page 21, lines 20-23). The formed matrix is then placed in the presence of the second reactant for the reaction to proceed so as to form the gas bubbles (page 18, lines 14-16). Gibbins et al (WO 01/49258) also specifically disclose the possibility of generating of carbon dioxide gas within the matrix by reacting an acid catalyst (which is similar to the viscous composition containing acid in the instant application) which is incorporated in the matrix followed by the perfusion of the matrix with a carbonate (page 15, lines 10-12).

*Finding of Prima Facie Obviousness Rationale and Motivation
(MPEP §2142-2143)*

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to make to impregnate the viscous composition of Tanaka into a sponge prior to reacting it with carbonate salt in stead of impregnation of the viscous composition for the liberation of carbon dioxide for external use into the sponge after reacting the viscous composition containing an acid with the carbonate salt, because Gibbins et al. as discussed above teach the recited mechanism. An ordinary skilled artisan would have been motivated to impregnate the viscous composition of Tanaka into a sponge prior to reacting it with carbonate salt, because the mechanism will help to eliminate the mixing prior to the impregnating as suggested by Gibbins et al. One of ordinary skill in the art at the time of the instant application

was filed would have had a reasonable expectation of success upon combining Tanaka et al and Gibbins et al, because both prior arts teach similar materials for the delivery of gaseous agents such as carbon dioxide via *in situ* production.

Response to Arguments

Applicant argued that the present invention is distinct from Tanaka et al (WO 99/24043) because the carbon dioxide in the present invention is in a substantially non-bubble state as opposed to Tanaka et al. in which carbon dioxide bubbles are formed. In the present invention, bubble formation is suppressed by an elastic polymeric three-dimensional network structure and by a viscous material. The examiner notes, as explained in the previous office action mailed on 05/13/08 and reiterated in the present office action, that both Tanaka et al. and the present invention comprise a viscous material containing carbon dioxide. Such a viscous material would inherently contain dissolved carbon dioxide (i.e. carbon dioxide in a non-bubble state). Although, as the applicant duly notes, Tanaka et al. also describes the presence of carbon dioxide bubbles. Because any carbon dioxide beyond the saturation limit of the base material would be in a gaseous state, the examiner notes that the present invention could produce gaseous carbon dioxide merely by increasing the amount of reactants used to produce carbon dioxide. Moreover, the examiner notes as the applicant points out in the arguments filed on 09/15/08 that it is not the generation of gaseous carbon dioxide in and of itself that is disadvantageous but the dispersion of carbon dioxide into the atmosphere as explained by the applicants' own specification. The important point, therefore, is the extent to which the viscous material disclosed by Tanaka et al. and the present invention traps carbon dioxide and effectively delivers said carbon dioxide to the treatment site—not the extent of bubble formation.

The second distinction noted by applicant between Tanaka et al and the present invention is the generation of carbon dioxide gas outside versus inside the absorbent material. In the examiner's opinion, this is not a patentable distinction. It would be obvious to the skilled artisan that carbon dioxide can be generated either within or outside of a viscous material such as that disclosed by Tanaka et al.. Moreover, the generation of a gas from reactants inside a matrix is already known in the art (Gibbins et al., WO 01/49258) as explained in the previous office action mailed on 05/13/08 and reiterated in the present office action.

The only remaining distinction between Tanaka et al and the present invention asserted by the applicants is the elastic polymeric three-dimensional network structure used in the base material of the present invention. While the elastic polymeric three-dimensional network structure used in the base material of the present invention may in fact further suppress formation of carbon dioxide bubbles over the viscous material alone, it is not sufficiently novel to warrant issuance of a patent. Moreover it is, in fact, disclosed by Tanaka et al. as explained in both the previous office action mailed on 05/13/08 and the present office action. Tanaka et al specifically disclose the use of an absorbent material such as a gauze or sponge (column 11, lines 4-5). Claims 18 and 21 as well as all the examples given in the applicants' specification use either a sponge or a nonwoven cloth. Although the applicants use the word "elastic" in the description of the present invention and Tanaka et al do not, there is no difference between the base material used by Tanaka et al and the polymeric network structure disclosed in the present invention.

The examiner agrees with the applicants that the reference Kenneth N. Anderson et al., *Mosby's Medical, Nursing, and Allied Health Dictionary* p1528 (Mosby 5th ed. 1998) was used by the examiner in the previous office action mailed on 05/13/08 and again in the present office

action for the definition of the word sponge. Just because the definition of the word sponge is not related to carbon dioxide generation does not make the definition irrelevant. The definition of the word sponge clarifies that both Tanaka et al and the instant invention disclose the use of a sponge or other similar polymeric network structure. Applicants indicate nothing in the claims that would differentiate the elastic polymeric three-dimensional network structure of the present invention from the materials disclosed in Tanaka et al.

Applicants fail to make any arguments against the relevance of Gibbins et al and merely assert that Gibbins et al. is further removed than Tanaka et al from the present invention. Determination of whether the invention disclosed by Gibbins et al is more or less closely related to the present invention than the invention disclosed by Tanaka et al is not a relevant consideration. The important point is that Gibbins et al is related to the present invention. The invention of Gibbins et al is directed to compositions, methods and devices comprising contact tissue materials for delivery of gases and other active agents (column 5, lines 36-38). Moreover, Gibbins et al disclose the generation of a gas inside a polymeric three-dimensional structure. Gases, including specifically carbon dioxide gas, are entrapped within the matrix. The invention of Gibbins et al is, as just discussed, substantially similar to both the present invention and to the invention disclosed by Tanaka et al. The invention of Gibbins et al clearly demonstrates that the generation and entrapment of gas from appropriate reactants inside a matrix is known and even, specifically, the generation of carbon dioxide inside a matrix such as that disclosed in the present invention is known. Therefore, the distinction between Tanaka et al and the present invention of generation of carbon dioxide outside versus inside the matrix is not unobvious but is disclosed by Gibbons et al.

Conclusion

Claims 13-24 are pending, while claims 1-12 are cancelled. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to TIGABU KASSA whose telephone number is (571)270-5867. The examiner can normally be reached on 9 am-5 pm Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Tigabu Kassa

12/19/08

/Johann R. Richter/

Supervisory Patent Examiner, Art Unit 1616